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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

GABEL, GAILENE

ART UNIT PAPER NUMBER

1641

DATE MAILED: 09/10/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application N .

09/227,518

Applicant(s)

TERRY ET AL.

Examiner

Gailene R. Gabel

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-- The MAILING DATE of this communication appears in the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 29 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 63-87 is/are pending in the application.
- 4a) Of the above claim(s) 64,65,75 and 76 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 63,66-74 and 77-87 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 63-87 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Amendment Entry***

1. Applicant's amendment and response filed 3/5/03 and 4/29/03 in Paper No. 21 and Paper No. 22 respectively, are acknowledged and have been entered. Claims 39-62 have been cancelled. Claims 63-87 have been added. Accordingly, claims 63-87 are pending.

### ***Election/Restrictions***

2. Newly submitted claims 63-87 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

- I. Claims 63, 66-74, and 77-87 are drawn to screening method wherein an array of compounds are disposed on a support, i.e. solid, for contact with viable cells.
- II. Claims 64, 66-73, 75, and 77-87 are drawn to screening method wherein an array of compounds are disposed specifically on a porous membrane for contact with viable cells.
- III. Claims 65-73 and 76-87 are drawn to screening method wherein an array of compounds are contacted with viable cells grown on a porous membrane.

Inventions I, II and III are distinct and independent inventions in that they have different structures having distinct modes of operation and different effects. Specifically, Invention I requires use of solid support upon which test compounds are disposed,

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Invention II requires use of porous membrane upon which test compounds are disposed, and Invention III requires that viable cells upon which test compounds are contacted, are grown on a porous membrane.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 64, 65, 75, and 76 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Accordingly, claims 63, 66-74, and 77-87 are under examination.

***Rejections Moot or Withdrawn***

3. The rejection of claims 39-62 are now moot in light of Applicant cancellation of the claims.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 63, 66-74, and 77-87 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 63, step c) lacks antecedent basis in reciting, "the liquid layer".

Claim 66 is vague and indefinite in reciting, "the porous membrane limits lateral spread of the test compounds during diffusion" because it is unclear, as recited, how relative "porosity" is able to limit lateral support.

Claim 74, step c) lacks antecedent basis in reciting, "the liquid layer".

Claim 77 is vague and indefinite in reciting, "the porous membrane limits lateral spread of the test compounds during diffusion" because it is unclear, as recited, how relative "porosity" is able to limit lateral support.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

5. Claims 63, 66-69, 71-74, 77-83, and 85-87 are rejected under 35 U.S.C. 102(e) as being inherently anticipated by Beutel et al. (US Patent 5,976,813).

Beutel et al. disclose continuous format high throughput screening (CF-HTS) of test compounds generated by combinatorial chemistry using at least one porous membrane (matrix) to allow an array of test compounds to be simultaneously exposed to a detector layer comprising physiologically viable cells (cell matrix) for detection of cellular response to the test compounds (see Abstract). The physiologically viable cells may be in a form of a monolayer and supported by an optically clear substrate, i.e glass

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or plastic (see Figure 4A and column 5, lines 52-60). Specifically, test compounds are disposed in an array onto a support which is a non-porous substrate (plastic sheet), then the support is contacted to the porous membrane so that the test compounds dissolve and diffuse into the matrix of the membrane (see column 6, 1-56, column 7, lines 7-59 and column 8, lines 12-25). Thereafter, the membrane is further brought into contact with the detector layer to allow the test compounds to diffuse into the cells contained in the detector layer. The detector layer is imaged to detect a response in the form of fluorescence or luminescence changes in the cells using spectrophotometric scanners, CCD cameras, and scintillation devices (see column 9, line 57 to column 10, line 16 and column 6, lines 53-56). According to Beutel et al. a central aspect of CF-HTS is that the porous membrane limits lateral diffusion of the test compounds during diffusion through the membrane.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

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under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 70 and 84 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beutel et al. (US Patent 5,976,813).

Beutel et al. differ from the instant invention in failing to disclose that the porous membrane is constructed of a non-absorbent material with pores of regular and defined diameter which traverse the membrane directly from the upper to the lower side.

However, Applicant, by way of disclosure at page 13 in the specification provides that these porous membranes, constructed of a non-absorbent material with pores of regular and defined diameter which traverse the membrane directly from the upper to the lower side, are well known, conventional, and commercially available, i.e. Immobilon (Millipore Corporation). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to substitute Immobilon membranes, having pores of regular and defined diameter which traverse the membrane directly from the upper to the lower side, for the porous membrane in the method of Beutel because these porous membranes are well-known and conventional and Beutel appears to be generic with the type of porous membrane used in the method.

7. For reasons aforementioned, no claims are allowed.

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8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (703) 305-0807. The examiner can normally be reached on Monday, Tuesday, and Thursday, 5:30 AM to 2:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.



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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-0169.

Gailene R. Gabel  
Patent Examiner  
Art Unit 1641  
September 5, 2003



CHRISTOPHER L. CHIN  
PRIMARY EXAMINER  
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